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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/299,521 04/09/99 BACHOVCHIN

W 19044-010

HM12/0829  
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EXAMINER

LUKTON, D

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/289,321

Applicant(s)

Bachovkin

Examiner

David Lukton

Art Unit

1653



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Apr 26, 2001

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1, 17, 35, 39, 71, and 72 is/are pending in the application

4a) Of the above, claim(s) 17, 39, 71, and 72 is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1 and 35 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

At the time of the restriction (paper No. 8, mailed 9/1/00), the observation was made that pursuant to the directives of paper No. 4 (filed 4/9/99), claims 2-16, 18-34, 36-38, 40-48, 50, 53-55 have been cancelled, and claims 57-70 added. Claims 1, 17, 35, 39, 49, 51, 52, 56-70 were regarded as pending at the time of the restriction. Subsequently, a paper was entered (paper No. 10, filed 10/10/00) which directed the cancellation of claims 49, 51-52, 56-70 and the addition of claims 71-72. Accordingly, claims 1, 17, 35, 39 and 71-72 are pending.

Applicants' election of Group 1 (claims 1 and 35) without traverse is acknowledged, as is the elected specie (the compound displayed in fig 1E).

Claims 17, 39 and 71-72 are withdrawn from consideration.

\*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

A CRF has been provided. However, there is at least one sequence unaccounted for. See, for example, the sequence on page 18d. (This corresponds to col 9, line 65 of U.S.P. 5,965,532).

In addition to the foregoing, 37 CFR 1.821-1.825 requires (or at least authorizes the

examiner to require) amendment of the specification to recite SEQ ID numbers.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

\*

Claims 1 and 35 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "capable of forming" renders the claim indefinite as to whether the forming takes place.

Claim 1 describes substituent variable "L" as a linker **molecule**. However, if "L" is indeed attached to A1 and A5, then "L" is not a separate, independent molecule. It is suggested that L" be described as a *linking group*.

In claim 1, clarity would be enhanced if the definition of each variable (that appears in the formula) were placed on its own separate line. A format such as the following could be used:

*wherein*

*D1 and D2 are independently selected from...*

*B represents...*

*A1 and A5 are independently selected from...*

*each of A2, A3, A4, A6, A7 and A8 is independently selected from...*

*X is an atom which forms a single or double bond with carbon or nitrogen*

*Y is an atom which forms a single or double bond with carbon or nitrogen*

*each of Y1, Y2, Y3 and Y4 is a hydroxyl group, or a substituent which is converted to a hydroxyl group under physiological conditions*

*L is a linking group which has a molecular weight within the range of 100-2000 Daltons...*

*the symbol "~" represents, independently for each occurrence, a single bond or a double bond.*

The same issues as above apply to claim 35 as well.

In claim 35, the meaning of R and R', and their relationship to the overall structure, is entirely incomprehensible. Significant revision of the claim is required. Is R' bonded to E1 or is R' not bonded to E1...? Is E1 bonded to "[J]" or is E1 not bonded to "[J]"...? Is E1 bonded to "[J]" at the same time that E1 is bonded to R', or is there some other mandate? If R and R' are necessarily part of the structural formula, they must be included.

In claim 35, it is stated that E1 undergoes a chemical reaction with E3. However, it is not possible for E1 taken by itself, to undergo a reaction with anything. In the structure,

E1 is bonded "[J]"; "[J]", in turn, is bonded to the rest of the molecule. In organic chemistry, it is an entire molecule that undergoes a chemical reaction. There is no provision for a fragment of a molecule undergoing a reaction, apart from the overall molecules itself. (Of course, it is possible for a molecule to "fragment", and for that fragment to undergo other reactions. However, once the fragment is formed, it then becomes a molecule unto itself).

\*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1 and 35 are rejected under 35 U.S.C. §103 as being unpatentable over Bachovchin (USP 5,776,902).

Bachovchin discloses (e.g., col 50, line 5+) peptidomimetics which contain one or more moieties that have phenylboronate sidechains. The reference does not provide the same generic formula as is recited in instant claim 1 or 35.

It might appear at first glance that none of A1-A4 or A5-A8 can form a ring. However,

given the elected specie, which contains a pyrrolidine group, it is evident that one or more of A1-A4 or A5-A8 can form a ring, or alternatively that two or more of A1-A4 or A5-A8 can form a ring.

It does not appear that the reference (USP '902) discloses a specific compound in which there are two boronic ester groups. However, as recited at col 50, line 5+, the disclosed compound contain "one or **more** amino acid residues" that have the recited "sidechains".

Thus, the claims are rendered obvious.

\*

The following references were stricken from the IDS because of the absence of a translation: DD 158109; DD 270382; DD296075; EP 0371467; EP 0,481311; EP 0,615978; EP 0,688788. The remaining references that were stricken from the IDS were so treated because a copy was not provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800